

# EXHIBIT A

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January 3, 2006

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CLIENT/MATTER NUMBER  
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Preston K. Ratliff II, Esq.  
Fitzpatrick Cella Harper & Scinto  
30 Rockefeller Plaza  
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Re: Biovail v. Andrx Pharmaceuticals LLC et al.,  
Civil Action No. 1:05-cv-586

Dear Preston:

We write in connection with Biovail's document production in response to Andrx's first set of document requests. The production consisted of less than four (4) boxes of documents bearing Bates Numbers BLS000001-BLS010076, and a single bottle of each strength of Biovail's finished product Cardizem LA tablets, labeled BLS Sample 001-BLS Sample 006.

Biovail's anemic production stands in stark contrast to Andrx's production of approximately 90,000 pages in approximately forty (40) boxes.

As a substantive matter, Biovail's production consisted of:

- (A) Andrx's notice letters and factual legal basis to Biovail. We do not understand why this would be included in your production, except possibly to try to pad Biovail's anemic production.
- (B) Biovail's NDA No. 21-392, which on its face incorporates by reference NDA No. 20-939 (which Biovail has not produced);
- (C) FDA correspondence regarding NDA No. 21-392 (but without the electronic documents submitted as attachments to several of those letters – see, e.g., BLS 005570);
- (D) Three Biovail "development reports" (at BLS 009772, 009843 and 009934);
- (E) A single article regarding wax beads as cushioning agents (at BLS 010010); and

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Preston K. Ratliff II  
January 3, 2006  
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(F) Two organization charts.

In light of the scope of Andrx's document requests, it appears that Biovail has "lost" a substantial number of relevant documents, or for some reason has decided that it need not produce those documents in accordance with the parties' agreement or the Federal Rules of Civil Procedure. In either event, we decline to further enrich Biovail by engaging in protracted letter-writing campaigns to dissuade you from your course. Either produce the documents immediately, or we will move to compel complete production in response to all pending requests, except numbers 35 and 49, which are the only requests to which Biovail appears to have made fully responsive production.

We also decline to play into Biovail's hands by being drawn into engaging in prolonged discussions about Biovail's non-responsive responses to Andrx's interrogatories. Either provide the requested information immediately, or we will move to compel the answers to which we were entitled in the first place.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Steven A. Maddox', written in a cursive style.

Steven A. Maddox

# **EXHIBIT B**

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January 11, 2006

VIA FACISIMILE

Steven A. Maddox, Esq.  
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3000 K Street, N.W.  
Suite 500  
Washington, DC 20007-5143

Re: *Biovail v. Andrx Pharmaceuticals LLC et al.*,  
Civil Action No. 1:05-cv-586 (KAJ)

Dear Mr. Maddox:

This is in response to Andrx's December 30, 2005 letter regarding Biovail's responses to Andrx's first set of interrogatories, and January 3, 2006 letter regarding Biovail's document production.

Regarding Biovail's responses to Andrx's first set of interrogatories, Andrx contends that Biovail's responses to Interrogatory Nos. 1-4, and 6-8 are insufficient. As to Interrogatory Nos. 1 and 4, Biovail has not refused to explain the bases for its allegation that Andrx infringes the '791 patent. In its responses, Biovail explained, among other things, that by virtue of Andrx's manufacturing process, beads of Andrx's tableted products will contain a wetting agent in admixture with one or more Diltiazem salts. In the spirit of cooperation, however, Biovail agrees to supplement its responses to Interrogatory Nos. 1 and 4 by January 20, 2006.

As to Interrogatory Nos. 2, 3, 6, and 7, none of the information requested is relevant to any issue in this case. Andrx's responses to Biovail's first set of interrogatories plainly demonstrate that Andrx has not raised any defense that would invoke the dates of conception, reduction to practice, or use of the inventions of the '791 patent, and that obviousness is not a defense in this case. Moreover, to the extent that Andrx actually has a need for the information it requested, Biovail identified persons knowledgeable regarding the conception and reduction to practice of the inventions of the '791 patent. Biovail therefore sees no reason to supplement its responses to Interrogatory Nos. 2, 3, 6, and 7.

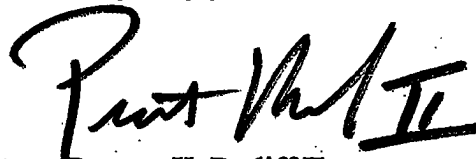
Steven A. Maddox, Esq.  
January 11, 2006  
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As to Interrogatory No. 8, Biovail has not refused to respond to this interrogatory. Interrogatory No. 8 seeks detailed technical information regarding the manufacture of Biovail's Cardizem LA products. Rule 33 permits reference to documents where the burden to ascertain the answer is substantially the same for each party. Biovail's response to this interrogatory states that information regarding the manufacture of Biovail's Cardizem LA products may be derived or ascertained from the "Chemistry, Manufacturing and Controls" section of Biovail's NDA for Cardizem LA, which was produced to Andrx on December 30, 2005. The burden of reviewing and analyzing this section of the NDA for Cardizem LA, is substantially the same for Andrx as it is for Biovail.

Regarding Biovail's document production, Andrx's statement that Biovail's production is "anemic" is disingenuous. When taken in consideration with all of the documents that Biovail produced to Andrx in the Tiazac® litigation, Biovail's entire production is indeed significant. The volume of Andrx's production is due largely to the fact that it reproduced many documents from the Tiazac® litigation. Moreover, another one-third of Andrx's production is raw data. As stated in its December 16 letter, Biovail is collecting, and will produce promptly additional documents regarding the research and development of its Cardizem LA products. Beyond those materials, please explain what additional documents Andrx seeks.

As to other complaints in Andrx's January 3, 2006 letter, Andrx states that it does not understand why copies of its Notice letters were included in Biovail's production. These letters were produced in response to Andrx's document requests. (See, for example Document Request No. 50.) Andrx complains that NDA 20-939 was not produced. That NDA, however, is directed to a different product, "once-daily Diltiazem Hydrochloride Extended-release" capsules. Please explain why Andrx believes NDA 20-939 is relevant to this case. Further, Andrx, citing only the December 20, 2001 letter found at BLS 005570-71, states that certain electronic attachments to letters were not produced. It is plain from the letter cited by Andrx that its attachments are directed solely to patient clinical data. Please explain how such documents are relevant to the issues in this case.

Very truly yours,

A handwritten signature in black ink, appearing to read "Preston K. Ratliff II". The signature is stylized with a large, sweeping "P" and a distinct "II" at the end.

Preston K. Ratliff II

cc: Via Facsimile

Jack B. Blumenfeld, Esq.  
William J. Cattie, III, Esq.  
Martin P. Endres, Esq.  
Herschel Sparks, Esq.

# EXHIBIT C





Specifically, the prior lawsuit addressed the issue of whether the beads employed in the Andrx Proposed Product contain an admixture of diltiazem and a wetting agent.

Second, this issue was actually litigated in the prior Biovail case. Biovail et al. had a full and fair opportunity to litigate the “admixture” issue in the prior lawsuit. More specifically, Biovail et al. were granted and conducted a full trial and an appeal on the admixture issue. Based upon these facts, Biovail et al. are barred under the doctrine of collateral estoppel from asserting that the beads of the Andrx Proposed Product infringe and claim of the '791 patent.

Third, United States District Court for the Southern District of Florida reached a valid and final decision on this issue. And the Federal Circuit Court of Appeals upheld that decision on appeal. *See Biovail Corp. Int'l. v. Andrx Pharm. Inc.*, 158 F.Supp.2d 1318 (S.D. Fla. 2000) *aff'd* 239 F.3d 1297 (Fed. Cir. 2001)

Fourth, the admixture issue was a critical and necessary part of the judgment in the first lawsuit. *Biovail*, 239 F.3d at 1301 (wherein the court stated “this case turns on whether the admixture limitation in [the claims of the] patent must be ‘homogeneous.’”)

For the above reasons, Andrx' Proposed Product will not infringe any claims in the '791 patent.

Finally, if the claims of the '791 patent are interpreted to include the Andrx Proposed Product, then the claims are invalid under 35 U.S.C. § 102(b) and/or 103(a) in view of the teachings of EPO 0 320 097 (EPO '097). The EPO '097 was published on June 14, 1989, more than one year before earliest filing date of the '791 and '505 patents (June 26, 1991), and discloses diltiazem beads prepared by applying to a sugar seed an admixture of diltiazem and an organic acid, then coating the diltiazem layer with an insoluble polymer, a water-soluble polymer, and a pharmaceutically acceptable adjuvant. EPO '097 also discloses that the pellets

can be compressed into tablets with excipients such as microcrystalline cellulose or sucrose.

Thus, if asserted as encompassing the Andrx Proposed Product, the claims of the '791 patent would read on the prior art, which is prohibited under the U.S. Patent Laws.

**INTERROGATORY NO. 2:**

For each claim of the '791 patent that Andrx contends is invalid, describe in detail the factual and legal bases for Andrx's contention.

**RESPONSE TO INTERROGATORY NO. 2:**

In addition to and without waiving the foregoing General Objections, Andrx objects to this Interrogatory to the extent that it asks for information protected by the attorney-client privilege or work-product immunity. Andrx also objects to this Interrogatory because it calls for legal conclusions. Finally, Andrx objects to this Interrogatory because it is premature.

Subject to the foregoing and the General Objections, Andrx hereby incorporates by reference its Response to Interrogatory No. 1.

**INTERROGATORY NO. 3:**

Identify whether Andrx requested, obtained, and/or conducted any opinions, studies, analyses, reports, tests or investigations, whether written or oral, relating to the validity or infringement (actual or potential) of any claim or claim element of the '791 patent (including but not limited to the claim element of "an effective amount of a wetting agent in admixture with the one or more Diltiazem salts"), or any related patent, either U.S. or foreign. If Andrx's answer is anything other than an unqualified "no," for each such opinion, study, analysis, report, test or investigation, identify:

# **EXHIBIT D**

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January 24, 2006

VIA FACSIMILE

Steven A. Maddox, Esq.  
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Suite 500  
Washington, DC 20007-5143

Re: *Biovail v. Andrx Pharmaceuticals LLC et al.*,  
Civil Action No. 1:05-cv-586 (KAJ)

Dear Mr. Maddox:

This concerns Andrx's responses to Biovail's first set of interrogatories, and Andrx's document production to date.

As to Andrx's responses to Biovail's first set of interrogatories, in response to Interrogatory No. 2 which seeks the bases for Andrx's invalidity contentions, Andrx only alleged invalidity based on a theory of anticipation despite its reference to 35 U.S.C. § 103(a). The statement of Andrx's allegation of anticipation is insufficient. Please supplement Andrx's response to Interrogatory No. 2 to state and explain in detail how each element of the '791 patent claims is disclosed in EPO 0 320 097. Further, if Andrx maintains that obviousness is one of its defenses, please supplement Andrx's response to Interrogatory No. 2 to state and explain the bases for Andrx's obviousness allegation, including but not limited to a full and complete explanation of: (1) the scope and content of the prior art; (2) the differences between the claims and the prior art; (3) the level of ordinary skill in the pertinent art; and (4) for each claim that Andrx asserts is obvious, the detailed reasons why that claim would have been obvious to one of ordinary skill at the time of the invention.

In response to Interrogatory No. 3, Andrx stated that it received a written opinion from Martin Endres relating to the '791 patent. As requested in that interrogatory, please identify whether that opinion relates to infringement or validity of the '791 patent. In addition, please supplement Andrx's response to include all of the information requested in paragraphs (a) through (i) of Interrogatory No. 3, including but not limited to the identification of the date of

Steven A. Maddox, Esq.  
January 24, 2006  
Page 2

opinion, the names of all persons who received copies of the opinion, all persons who participated in the opinion, all documents and things identified or considered in the opinion, and the results or conclusions of the opinion.

As to Andrx's document production, Andrx has failed to produce many requested documents. Notably absent from Andrx's document production are reports (summary or otherwise) regarding the development of its proposed tableted products. In addition, Andrx has not produced any correspondence and meeting minutes regarding the early work that led to the development of its proposed tableted products. Attached at Tab A is a chart identifying documents that Andrx has failed to produce. If Andrx does not agree to promptly produce the requested documents, Biovail will seek the Court's assistance to obtain the documents it is entitled to.

Very truly yours,

A handwritten signature in black ink, appearing to read "Preston K. Ratliff II". The signature is fluid and cursive, with the first name "Preston" and last name "Ratliff" being more legible than the middle initial "K." and the suffix "II".

Preston K. Ratliff II

cc: Via Facsimile

Jack B. Blumenfeld, Esq.  
William J. Cattie, III, Esq.  
Martin P. Endres, Esq.  
Herschel Sparks, Esq.